



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

52

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,551	11/27/2001	Jamie S. Henderson	498-269	8199
7590 12/02/2004			EXAMINER	
Ludomir A. Budzyn HOFFMAN & BARON, LLP 6900 Jericho Turnpike Syosset, NY 11791			BIANCO, PATRICIA	
			ART UNIT	PAPER NUMBER
			3762	
DATE MAILED: 12/02/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/994,551

Applicant(s)

HENDERSON ET AL.

Examiner

Patricia M Bianco

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 6-11, 14-17 and 21-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 12, 13 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: Final Rejection.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-5, 12, 13, & 18-20 have been considered but are moot in view of the new ground(s) of rejection.

Election/Restrictions

Claims 6-11, 14-17 & 21-56 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention & Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in paper filed 4/9/04.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3762

Claims 1-4, 12, 13, & 18-20 are rejected under 35 U.S.C. 102(b) as anticipated by Kalis (5,609,624). Kalis discloses a vascular graft that is tubular 10, has an interior surface defining a lumen therethrough, an exterior surface 12, and a plurality of ribs 14, which are uncovered for direct contact with tissue. Kalis further teaches that the entire graft is made of ePTFE, which is biocompatible. With respect to claim 12 specifically, the ribs are adhered to the surface of the tubular body and, therefore, will inherently have a sealant material adjacent to the ribs. With respect to claim 13, Kalis also teaches that the ribs 58 may be in a helical direction along the tubular body (see figures 6-8). Further, the helical ribs stop at a given distance from the ends, therefore, they are not coextensive with the tubular body.

Claims 1-4, 12, 13, 18 & 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Knapp et al. (5,984,965). Knapp et al. disclose a stent device 10 that has a tubular body 12, has an interior surface defining a lumen 24 therethrough, an exterior surface, and a plurality of filaments 18 (i.e. ribs), that are uncovered for direct contact with tissue. Knapp et al. also teach that the entire graft is made of a biocompatible, polymeric material. With respect to claim 12 specifically, the filaments (ribs) are adhered to the surface of the tubular body and, therefore, will inherently have a sealant material adjacent thereto. With respect to claim 13, the filaments (ribs) are not longitudinally disposed along the body, but extend out at an angle, therefore, they are not coextensive with the tubular body.

Art Unit: 3762

Claims 1-5, 12, 13, 18 & 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Phan et al. (5,129,910). Phan et al. disclose a stent device 1 that has a tubular body 10, has an interior surface defining a lumen 22 therethrough, an exterior surface, and a plurality of ridges 25/225/325 (i.e. ribs), that are uncovered for direct contact with tissue. Phan et al. also teach that the entire graft is made of a biocompatible, polymeric material. With respect to claim 12 specifically, the ridges (ribs) are adhered to the surface of the tubular body and, therefore, will inherently have a sealant material adjacent thereto. With respect to claim 13, the ridges 325 (ribs) are non-continuously disposed along the body, extending out at an angle, and therefore, they are not coextensive with the tubular body. With respect to claim 5, Phan et al. teaches that the tubular body may include one or more tubular members (col. 5, lines 62-64) which is seen to be equivalent to a sleeve being formed with the tubular body.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

Art Unit: 3762

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knapp et al. ('965) in view of Kalis (624). Knapp et al. disclose the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the ribs are made of expanded polytetrafluoroethylene (ePTFE). Kalis discloses a vascular graft that is tubular, having ribs, wherein the rib structures are ePTFE. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Knapp et al. to make the ribs of ePTFE as taught by Kalis, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Phan et al. ('910) in view of Kalis (624). Phan et al. disclose the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the ribs are made of expanded polytetrafluoroethylene (ePTFE). Kalis discloses a vascular graft that is tubular, having ribs, wherein the rib structures are ePTFE. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Phan et al. to make the ribs of ePTFE as taught by Kalis, since it has been held

Art Unit: 3762

to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

Art Unit: 3762

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 28th, 2004

Patricia M Bianco
Primary Examiner
Art Unit 3762


PATRICIA BIANCO
PRIMARY EXAMINER